Healthcare Improvement Scotland | SHTG Advice on health technologies

Advice Statement 012-18
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Advice Statement

Outpatient biopsy, for diagnosis of suspicious lesions of the larynx, pharynx and tongue base

Advice for NHSScotland

Outpatient biopsy has a low rate of complications and, in most cases, sufficient tissue for pathological examination can be obtained. Where there strong clinical suspicion of malignancy, outpatient biopsy offers the possibility of a more rapid diagnosis and allows selected patients to avoid biopsy under general anaesthetic in the operating theatre. The provision of outpatient biopsies is also likely to reduce laryngoscopy costs to the NHS, although initial investment will be required to purchase the additional equipment needed to obtain biopsies in the outpatient setting.

NHSScotland is required to consider the Scottish Health Technologies Group (SHTG) advice.

Why is SHTG looking at this topic?

The incidence of head and neck cancer is increasing. Reducing diagnostic delay is essential since early detection can improve prognosis and/or enable early initiation of appropriate care.

The topic was prioritised for inclusion on the SHTG programme following topic referral from Queen Elizabeth University Hospital, NHS Greater Glasgow and Clyde

Evidence Note 84 was produced by Healthcare Improvement Scotland in response to this request.

Background

Patients referred to ear, nose and throat (ENT) or head and neck outpatient clinics commonly undergo transnasal endoscopy to visualise the larynx, pharynx and tongue base. When suspected malignant lesions are identified, the 'gold standard' investigation is direct laryngoscopy under general anaesthetic in the operating theatre. In addition to anaesthetic risk, this carries risk of dental damage, and in some cases, requirement for

tracheostomy. The need to schedule theatre time, an overnight or day-case hospital bed and pre-procedure assessment contributes to potential delay in commencing appropriate care.

Developments in technologies for transnasal endoscopy include the incorporation of an instrument channel through which biopsy forceps may be used. In addition to this, image processing systems which provide visual enhancement through colour filtering may improve identification of malignancy. These developments mean that, for some patients, a biopsy can be taken, under local anaesthetic, at the time of initial outpatient investigation.

Clinical effectiveness

- Most studies of outpatient biopsy were retrospective, and none of the diagnostic test accuracy studies comparing outpatient biopsy with operating theatre biopsy used the most up to date imaging technology.
- Sensitivity and specificity results from the largest prospective study were typical of the evidence base, at 71% and 97% respectively for identifying malignancy in patients with suspicious laryngeal and pharyngeal lesions when compared with the gold standard of biopsy under general anaesthetic in the operating theatre.

Safety

- Outpatient biopsy was generally found to be safe with low complication rates. Although most complications were minor and self-limiting, one case of subglottic oedema requiring tracheostomy was described in the literature.

Cost effectiveness

- Five studies identified within the literature reported cost items as a study outcome (of which two had conducted formal cost and/or reimbursement comparisons). The data from three studies were not applicable to a Scottish setting and the remaining two studies did not report sufficient methodological details to determine their relevance to a Scottish setting and could not be used. Nevertheless, it is notable that where comparative costs of the procedures were reported, outpatient biopsy was consistently cheaper than operating room biopsy.
- Healthcare Improvement Scotland developed a budget impact model to inform use of this technology in NHSScotland. Owing to the current evidence relating to the diagnostic accuracy of outpatient biopsy, the model assumes that those who test negative will require operating theatre biopsy to confirm the result. It also assumes that a small number of patients may experience complications from either procedure, and that in some cases outpatient biopsy may not be tolerated by the patient, in which case operating theatre biopsy under general anaesthetic will be needed.

- The results of the analysis found outpatient biopsy to be resource-saving over a period of five years. Accounting for initial investment costs of approximately £1.5m in the first year and on-going annual costs of £200,000, the average resource saving per annum over five years was in excess of £400,000.

Patient and social aspects

- A large prospective study (n=117) found the outpatient biopsy procedure to be well tolerated by patients in that adequate tissue for pathological examination was obtained in 94% of cases.
- The procedure may be unsuitable for patients who are not able to sit for a prolonged time, have a strong gag reflex or have respiratory distress or poor cardiopulmonary function.

Context (includes organisational issues)

- In NHS Greater Glasgow and Clyde (NHS GG&C), the ENT department performs over 700 general anaesthetic operating theatre biopsies each year.
- Based on an NHS GG&C departmental audit, 20-30% of patients who have head and neck cancer will be offered treatment with palliative intent at diagnosis.
- The availability of the outpatient biopsy procedure is currently limited to a small number of Scottish centres.

Further research

- Current evidence on transnasal endoscopy with biopsy appears to be at the assessment stage of the IDEAL framework.
- A large prospective study to investigate patient experience of outpatient biopsy, and to further assess sensitivity and specificity where enhanced imaging technology is incorporated, would add to the evidence base.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full. This advice represents the view of the SHTG at the date noted.

It is provided to inform NHS boards in Scotland when determining the place of health technologies for local use. The content of this Advice Statement was based upon the evidence and factors available at the time of publication. An international evidence base is reviewed and thus its generalisability to NHSScotland should be considered by those using this advice to plan services. It is acknowledged that the evidence constitutes only one of the sources needed for decision making and planning in NHSScotland. Readers are asked to consider that new trials and technologies may have emerged since first publication and the evidence presented may no longer be current. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgment in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

SHTG Advice Statements will be considered for review if new evidence becomes available which is likely to materially change the advice. Stakeholders may submit a request, highlighting new evidence to shtg.hcis@nhs.net

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Chair
Scottish Health Technologies Group

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